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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,585	10/12/2000	Ger Van den Engh	Cyto-Nozzle-Div	2640

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EXAMINER

LUDLOW, JAN M

ART UNIT

PAPER NUMBER

1743

10

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/689,585

Applicant(s)

ENGH, GER VAN DEN

Examiner

Jan M. Ludlow

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83-110 is/are pending in the application.
- 4a) Of the above claim(s) 97-110 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 83-87, 89, 91, 92 and 94-96 is/are rejected.
- 7) ☒ Claim(s) 88, 90 and 93 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 April 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. Applicant requests rejoinder of claims 97-100, but applicant has still not made the method claims include all of the limitations of the apparatus claims and the request is therefore denied.

2. Claim 94 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure that is not enabling. A flow cytometer nozzle of the claimed structure and having an oscillator powered by less than 100 mV, but not requiring direct coupling of the oscillator to the fluid (p. 11, lines 14-17), unidirectional coupling of the oscillator (p. 13, lines 2-4) and/or continuous convergence of the nozzle body (p. 14, lines 13-15), which are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant has not enabled one of ordinary skill in the art to make or use a nozzle of the claimed structure that uses less than 100 mV to the oscillator in that the disclosure does not teach that the manner of attaching the tip imparts any of the energy savings (p. 16, paragraph 3). Claim 94 lacks all three features that contribute to the energy savings. Applicant has not shown or described that the claimed seal alone will produce a low energy usage nozzle.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 83-86, 89, 91-92, 94-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollinger et al (4515274).

Hollinger teaches a nozzle body 14 with sheath 23B and sample 23A inlets. Nozzle tip 16, 24 is joined to the body. A structure (medium hatching between outside of 16 and interior surface of 14) is between the body and tip. There is a joint between the body and tip at the inner edges of the top of part 16, constituting the instant "edge insert". Portion 18 is convergent near the sample outlet (instant "flow convergence zone"). A piezoelectric oscillator 36 coupled unidirectionally (i.e., laterally) to part 14 is provided. In that the seal is located as claimed, i.e., is off the inner surface of the nozzle tip (by virtue of being located outside of tip portion 16), it is the examiner's position that the seal does not impact laminar flow as claimed, since it is not in contact with the flow path at all.

Hollinger fails to teach that the parts are sealed or the claimed power source.

It would have been obvious to seal the parts of Hollinger together in order provide a leak-free flow path to minimize loss of sample, sheath fluid and/or pressure in the closed system. It would have been obvious to provide a power source to power the piezoelectric crystal with minimum power in order to make it oscillate as described.

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6. Claims 88, 90 and 93 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: Hollinger fails to teach or suggest a directional isolator located between the oscillator and the nozzle body, a sample fluid inlet position adjuster or continuously convergent tip and body.

8. Note that Sage ('971) teaches sample tube lateral adjustment, but that there is no motivation to combine with Hollinger in that the nozzle body structures are significantly different.

9. Note that Buchanan et al ('745) teach a tip attached similarly to that of the instant invention, but does not constitute prior art.

10. Applicant's arguments filed April 3, 2002 have been fully considered but they are not persuasive.

11. With respect to the scope of enablement rejection, applicant's arguments are persuasive with respect to claim 87, but not with respect to claim 94. The examiner has cited specific portions of the instant disclosure in which applicant specifically teaches that the specific features cited by the examiner contribute to the energy savings. Thus, the examiner concludes at least one of these features is required to impart the claimed energy savings. Applicant has pointed to no portion of the specification supporting the position that these features are not required for the energy savings, or that the instantly claimed seal in any way contributes to the energy savings. The instantly claimed seal is described as an independent feature that permits the nozzle to be easily replaced or cleaned while permitting laminar flow (p. 16, paragraph 3).

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12. With respect to Hollinger, applicant has argued that the examiner has not addressed the location of the seal, but the examiner has specifically pointed to the structure between the outer surface of the top part of the nozzle tip 16 and an inner surface of the nozzle body 14. Applicant argues that the mere existence of the structure of Hollinger does not make certain or disclose the location of the tip-to-body seal and that fluid parameters may impact the seal location, including the possibility that the seal might exist "at the juncture on the inner surface between the body and the tip." This argument is not persuasive because no surface of the body 14 is in contact with the inner surface of the upper portion of the tip, element 16. In fact, no element of Hollinger is in contact with the inner surface of the upper portion of the tip 16 or the bottom portion of the tip 24. A flat horizontal surface of 14 contacts the top ("off the inner") surface of 16 and a vertical inner notch surface of 14 contacts the outside ("off the inner") surface of 16 via a hatched element that, while not described, has the logical placement of a round gasket or ring. Since none of the potential seal surfaces is in contact with the flow path, it is the examiner's position that laminar flow is not impacted by the seal. Note that the instant disclosure repeatedly discloses sealing between the nozzle body and tip in the prior art and applicant has not argued the obviousness of sealing the parts of Hollinger together in order provide a leak-free flow path to minimize loss of sample, sheath fluid and/or pressure in the closed system. It is, after all, a flow system and one of ordinary skill in the art would expect it to be designed not to leak.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

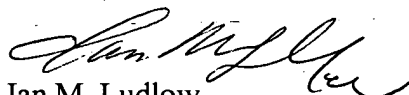
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml
June 16, 2003